

Remarks

Claims 23-27, 31, 33, 36, 37, and 39-46 are pending in the subject application. By this Amendment, Applicants have canceled claim 44, amended claims 23, 39, 42, 43, and 45, and added new claims 47-54. Support for the new claims and amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 23-27, 31, 33, 36, 37, 39-43, and 45-54 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claim 36 is objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

The Office Action indicates that the executed inventor's Declaration submitted by Applicants is defective and that a new oath or declaration is required. Applicants respectfully submit that the executed Declaration submitted in the subject application is not defective. The difference between the "correct" and "incorrect" statements in the Declaration are the words "the" and "(a)", which Applicants assert are not significant differences. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claim 37 is rejected under 35 USC §112, second paragraph, as indefinite in regard to the reference to "vertical movements" in the claim. Applicants respectfully assert that the claim is clear and definite. However, by this Amendment, Applicants have amended claim 37 to clearly define that the accelerometer is oriented so as to sense movement of the user's chest or torso in a direction substantially parallel to the user's spine when the user is in a standing position. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 23, 25, 31, 39, 42, 45, and 46 are rejected under 35 USC §102(b) as anticipated by Ohtake (U.S. Patent No. 5,483,967) and claims 26, 27, and 41 are rejected under 35 USC §103(a) as obvious over the Ohtake patent. The Examiner asserts that the Ohtake patent teaches a bioelectrical signal recording device that includes a base member which has an adhesive side that serves to adhere the base member to the body of a patient. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully assert that the Ohtake patent does not teach or suggest the claimed invention. By this Amendment, claims 23, 39, 42 and 45 have been amended to specify that the monitor, or cardiac sensor, is releasably attachable to a single adhesive ECG electrode. Where appropriate, claims have also been amended to specify that the monitor is releasably electrically couplable to a second ECG electrode. Applicants respectfully assert that the amendments presented herein further highlight distinctions between the monitor of the present invention and that of the Ohtake patent.

In the Ohtake patent, a bioelectrical signal recording device comprises a flexible, sheet-like base member in which one or a plurality of electrodes is/are mounted, and electrically connected to a recording element, which is also mounted within the sheet-like base member. As described at the beginning of column 2 of the Ohtake patent, the device is used “merely by sticking the recording device on the body”. Further, at column 2, lines 22 to 28, of the Ohtake patent, it is stated that the living-body electrical signal recording device is stuck “as one unit on the body” so that “even a beginner can obtain correct records ... by a simple sticking operation”. Clearly, the recording device of the Ohtake patent is a unitary device. By contrast, the present application describes a monitor in which conventional, or standard ECG electrodes are used. In particular, an ECG electrode is stuck to the body and the monitor is then coupled, both mechanically and electrically, to the ECG electrode. This provides a significant advantage over the device of the Ohtake patent in that standard ECG electrodes can be used. The Ohtake patent does not teach or suggest the use of standard ECG electrodes with the Ohtake device.

In order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Similarly, to render an invention obvious, the cited reference(s) must teach or suggest each and every element and limitation of the rejected claim. Applicants respectfully assert that there is no teaching or suggestion in the Ohtake patent of each and every element of Applicants’ claimed invention. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102(b) and §103(a) is respectfully requested.

Claims 33, 37, 40, 43, and 44 are rejected under 35 USC §103(a) as obvious over Ohtake (U.S. Patent No. 5,483,967) in view of Kristbjarnarson (U.S. Patent No. 6,049,730). The Ohtake patent is cited as discussed above. The Examiner notes that the Ohtake patent does not teach or suggest use of an accelerometer to generate movement data. The Kristbjarnarson patent is cited as teaching a monitor for monitoring a user's heart and that the monitor comprises an accelerometer. Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the cited references, whether taken alone or in combination, do not teach or suggest the claimed invention. The Kristbjarnarson patent describes a heart-rate monitor system in which a user carries a heart-rate monitor, for example hanging on a strap over the user's shoulder (see Figure 8 of the Kristbjarnarson patent). The monitor is coupled by electrical leads to sensors such as ECG pads. The monitor can thus record heart rate. The Kristbjarnarson device also houses an inclinometer within the monitor, to record the orientation of the user's body, that is, for example, whether the user is standing up or lying down. This is apparently because the body orientation influences the precise position of the heart within the user's torso and the Kristbjarnarson patent indicates that the ECG signal received by the monitor can be handled differently depending on the orientation of the user's body. Although the Kristbjarnarson patent states that the inclinometer may comprise accelerometers having three orthogonal axes (see column 3, line 51, of the Kristbjarnarson patent), the patent also states that the accelerometers are sensitive to the earth's gravitational force. This reveals the true function of the accelerometers in the Kristbjarnarson device, which is simply to identify a vertical direction (rather than movement) relative to which the orientation of the user's body can be assessed.

In contrast, the accelerometer in the present invention is for generating activity data, or movement data, in order to evaluate the physical activity of the user. In one embodiment, a monitor of the invention comprises only one accelerometer for measuring acceleration in one direction, namely to sense vertical movement of the user's torso (*i.e.*, movement parallel to the user's spine, which is found by the inventors to be the optimum orientation for monitoring the user's physical activity). This accelerometer would not provide the signal required by Kristbjarnarson. First, if the user is stationary, in any orientation, then the accelerometer will provide no output because there is no acceleration. Second, because the accelerometer is uniaxial, it would be insensitive to

accelerations in other directions. Consequently, the accelerometer of the present invention would not function as an inclinometer as required in the Kristbjarnarson device. Further, in order to generate activity or movement data, it is important for the accelerometer to be securely mechanically coupled to the user's body. In the Kristbjarnarson device, as illustrated in Figure 8 of the Kristbjarnarson patent, the monitor is merely suspended from the user's body by a shoulder strap and would not necessarily follow the body's movement with any degree of reliability. Accordingly, Applicants respectfully assert that the "inclinometer containing accelerometer sensors" in Kristbjarnarson is not comparable to the accelerometer for generating activity data in the present invention.

The Examiner also indicates, starting at the foot of page 6 of the Office Action and continuing to page 7, that "Kristbjarnarson teaches that it is known in the art to include an activity or movement sensor such as an accelerometer in an ambulatory physiological recorder". Applicants respectfully assert that the Kristbjarnarson patent does not teach or suggest that it is known to include "an activity or movement sensor". The Kristbjarnarson patent only teaches the use of an inclinometer in an ambulatory physiological recorder.

As the Examiner is aware, it is well established in patent law that in order to support a *prima facie* case of obviousness, a person of ordinary skill in the art must find both the suggestion of the claimed invention, and a reasonable expectation of success in making that invention, in light of the teachings of the prior art or from the general knowledge in the art. *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion, nor the reasonable expectation of success, of Applicants' claimed invention in the cited references. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Petition and Fee for Extension of Time Under 37 CFR §1.136(a)
Amendment Transmittal Letter